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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/009,846 01/20/98 ZAMBIAS

R 5925-061-999

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HM12/1222

EXAMINER

PONNALURI, P

ART UNIT

PAPER NUMBER

1618

DATE MAILED:

12/22/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

19

Office Action Summary

Application No.
09/009,846

Applicant(s)

Zambias et al

Examiner

P. Ponnaluri

Group Art Unit

1618



☒ Responsive to communication(s) filed on Oct 4, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-7, 10-13, and 16-25 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-7, 10-13, and 16-25 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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1. The amendment filed on 10/4/99 has been fully considered and entered into the application.
2. New claims 16-25 have been added and claims 8-9, 14-15 have been canceled by the amendment filed on 10/4/99.
3. Claims 1-7, 10-13 and 16-25 are currently being examined in this application.
4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: signature of one of the inventors is missing.

The copy of the petition to correct the inventor ship of this nonprovisional application under 37 CFR 1.48(a) and declaration filed in parent application is not sufficient in the divisional applications. Applicants are requested to file a separate petition in the instant application.

5. The rejection of claims 1-9 under 35 U.S.C. 101, and under 35 U.S.C. 112, first paragraph for lack of specific asserted utility or a well established utility, set forth in the previous office action has been withdrawn in view of applicants arguments.
6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-7, 11-13, 16-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for

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failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, 10, 11, and 22 is vague and indefinite by reciting 'spatially addressable array.' It is not clear how the compounds in the array differ from each other in the spatially addressable array, since the molecular core of the compounds is the same, and the structural diversity elements are not defined. Claims 1, 10, 11 and 22 are vague and indefinite by reciting 'structural diversity elements', it is not clear what does applicant mean by structural diversity elements.

Claim 10 is vague and indefinite by reciting 'a) providing a plurality of reaction vessels organized into the first and subarray...', it is not clear how the reactants will be added to the vessels in the subarray form the compounds of the array. The subarrays are separated by the vessels, how will they form a single array. Does applicant refer to each subarray as an array. It is very confusing. Applicants are suggested to clarify.

Claims 11 and 22 are vague and indefinite by reciting 'apportioning into reaction vessels that are identifiable by their spatial addresses', it is not clear what does applicant mean by spatial address, does it mean the location of the vessel or some kind of numbering. The step b) in the claim does it mean that all the first and second compounds in each reaction vessels are added together into one so that one single array of compounds is formed, applicants are requested to clarify.

Claim 12 is vague and indefinite by reciting '.....formatting the contents of the reaction vessels into a spatially-addressable array.', it is not clear how the contents of the reaction vessels

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is formatted into spatially addressable array. Does it mean that after the reactions are completed the compounds are rearranged.

Claim 24 is vague and indefinite by reciting 'wherein the reagents of at least 80 reaction vessels are concurrently reacted..', it is not clear which 80 reaction vessels out of 500 are reacted per cycle.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-2, and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,510,240 (Lam et al).

Lam et al teach a library of biooligomers of defined size, in which the library contains all the possible sequences of the biooligomers and a method of synthesis thereof. The bio-oligomers

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of the library may be peptides (comprising amino acids, amino acid analogs, peptido mimetics, designer amino acids) (refers to different compounds), nucleic acids, or a combination thereof. The amino acids have carbon, nitrogen and oxygen in the structure, and they differ from one another by the side chain groups. The reference teaches that the bio-oligomers of the library are cleavable, and the bio-oligomers from the beads in solution phase are cleaved and released into the wells of a microtiter plate (refers to spatially addressable array in solution of the instant claims). The reference teaches that the method allows only one species of peptide on each bead, thus when they are cleaved from the bead into the solution in a microtiter well, each well would have one species of peptide (refers to the compounds are unique). The reference teaches that the method is applicable to permit the synthesis of a random peptide pool with 10^5 to 10^7 different peptide species. The reference teaches methods of screening the compounds present in the library by cleaving them into the solution, such that the library is screened for different biological properties, and intact cells or receptors attached to cell membranes could be used as receptors. The claimed invention differs from the prior art teachings by reciting a spatially addressable array of 500 different compounds. However, Lam et al teach that the method is applicable to permit the synthesis of a random peptide pool with 10^5 to 10^7 different peptide species. The oligomers when they are cleaved from the beads into the solution of wells of microtiter plate, read on the spatially addressable array of compounds. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the library using the method disclosed by Lam et al and cleave the compounds (peptides) into the solution. It would have been obvious to one of

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ordinary skill in the art at the time the invention was made to motivated to use the method of making the peptide library taught by Lam et al to synthesize a library of different molecules.

10. Claims 1-7 and 11-13 and 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pirrung et al (J. Am. Chem. Soc. January 1995, vol. 117, pages 1240-1245).

Pirrung et al teach indexed combinatorial methods of preparing and screening compounds. The reference teaches that the indexed combinatorial library methods are applicable to any molecule that can be assembled in a simple chemical process from multiple subunits. The reference teaches that the disclosed method provides a significant reduction in the effort needed to synthesize and test large numbers of compounds that can be composed of N-different building block sets. The reference teaches a combinatorial library composed of 54 carbomates and the most active member of the library is identified by preparing 15 sublibraries in which one of the reacting component was fixed and the other reactants were used as an equimolar mixture. The product mixture was tested and their activities used as "indices" to the rows or columns of a two-dimensional matrix reflecting the activities of individual compounds. A number of carbamates in the most active row and column were synthesized and assayed, demonstrating that the most active cell in the matrix could be identified by the sublibrary synthesis procedures. The reference teaches that the library can be represented as N-dimensional matrix (see figure 1) (refers to spatially addressable array in solution of the instant claims) wherein each axis has as many elements as are present in each set. The reference teaches that the building blocks used in the disclosed method are alcohols and isocyanates (see figures 2 and 3). The building blocks have at least carbon,

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nitrogen and oxygen. The reference teaches that using 70 building blocks, a library of over 800 compounds can be made. The claimed invention differs from the prior art teachings by reciting that the array has 500 different compounds. However, Pirrung et al teach using the disclosed method can be applicable to any molecule that can be assembled in a simple chemical process from multiple subunits, and the size of the library is dependent on the different N building blocks used. Thus, it would have been obvious to one of ordinary skill in the art use the solution phase combinatorial method taught by Pirrung et al in synthesis of spatially addressable array of 500 different compounds, because Pirrung et al teach that the size of the library depends on the N different building blocks.

11. Applicant's arguments with respect to claims 1-9 have been considered but are moot in view of the new ground(s) of rejection.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

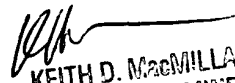
Any inquiry concerning this communication should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald Adams, can be reached at (703)308-0570. The fax number for this group is (703)308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0916.

P. Ponnaluri

December 19, 1999


KEITH D. MacMILLAN
PRIMARY EXAMINER